INFORMED CONSENT PROCEDURES

1. PURPOSE AND SCOPE: This handbook is being re-issued without changes to permit recertification of the policy while it is being more extensively reviewed and revised. It contains requirements for informed consent, the process essential to promoting informed decision making by the patient, and defines the obligations of healthcare staff.

2. SUMMARY OF CONTENTS/MAJOR CHANGES: No changes are being made in this policy at this time.

3. RELATED ISSUES: None.

4. RESPONSIBLE OFFICE: National Center for Clinical Ethics (10AE). Questions are to be addressed to the National Center for Clinical Ethics at (802) 296-5145.

5. RESCISSIONS: VHA Handbook 1004.1, dated August 1, 1996, and VHA Handbook 1004.1/1, dated November 27, 1997, are rescinded.

6. RECERTIFICATION: This document is scheduled for recertification on or before the last working day of November 2003.

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DISTRIBUTION: CO: E-mailed 11/7/2001
FLD: VISN, MA, DO, OC, OCRO, and 200 – E-mailed 11/7/2001

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1. PURPOSE

This handbook describes the criteria for informed consent and the process essential to promote "informed" decision-making by the patient. It also defines the obligations and duties of the health care staff. The staff must assure that the patient is given sufficient information to make an informed decision concerning the available treatment options.

2. BACKGROUND

The Department of Veterans Affairs (VA) is committed to providing a health care environment that recognizes the patient's right to self-determination (autonomy). Respect for patient autonomy is an essential component of quality health care and is consistent with the highest ethical and medical standards. VA's informed consent policy seeks to promote communication between the patient (or the patient's surrogate) and the health care team to help the patient achieve appropriate health goals.

3. SCOPE

It is Veterans Health Administration (VHA) policy that VA patients may accept or refuse any treatment offered to them. Except as otherwise provided in this Handbook, diagnostic and therapeutic treatments or procedures must be undertaken only with prior, informed consent of the patient. In order to give informed consent, the patient, or the patient's surrogate decision-maker, hereafter referred to as "surrogate" must understand the nature of the treatment or procedure to be undertaken, the benefits and risks of the treatment, the alternatives to the proposed course of action, and the expected outcome if the treatment is declined. The practitioner must explain this information in language the patient can understand. The patient must be allowed to ask questions and to make a decision freely without coercion or duress. The consent process is completed by appropriate documentation in the medical record.

a. **Discussion of Risks**. Every treatment or procedure, regardless of how minor, involves some risk. As part of good medical practice, the treating practitioner must advise the patient of these risks as well as the benefits of treatment. Signature consent is not required; e.g., to administer most drugs or perform minor procedures; however, the practitioner must document in a progress note that the treatment or procedure and its indications were discussed with the patient.

b. **Criteria for Signature Consent**. In addition to the informed consent discussion, the patient's signature of consent must be obtained for all diagnostic and therapeutic treatments or procedures that:

(1) Require the use of sedation,

(2) Require anesthesia or narcotic analgesia,

(3) Are considered to produce significant discomfort to the patient,

(4) Have a significant risk of complication or morbidity,

(5) Require injections of any substance into a joint space or body cavity,

(6) Involve testing for human immunodeficiency virus (HIV), and

(7) Are listed in Appendix A.

4. DEFINITIONS

a. **Decision-Making Capacity**. Decision-making capacity is the ability to understand and appreciate the nature and consequences of health care treatment decisions. This includes understanding the benefits and risks of the proposed treatment options, as well as any alternative treatment options.

b. **Lack of Decision-Making Capacity.** Lack of decision-making capacity is the inability to understand and appreciate the nature and consequences of health care decisions and to formulate and/or communicate decisions concerning healthcare. Patients who are incapable of giving consent as a matter of law; e.g., persons judicially determined to be incompetent, are deemed to lack decision-making capacity for the purpose of obtaining informed consent.

c. **Practitioner**. A practitioner is any physician, dentist, or health care professional who has been granted specific clinical privileges to perform the treatment or procedure involved. For the purpose of obtaining informed consent for medical treatment, the term practitioner includes medical and dental residents regardless of whether they have been granted clinical privileges.

d. **Risks.** Risks are the possible outcomes of a treatment or procedure categorized as follows:

(1) Known side effects or consequences. Predictable outcomes of a particular treatment or procedure; e.g., pain after surgery.

(2) Possible side effects or consequences. Outcomes that are not certain to happen as a result of a particular treatment or procedure, but that commonly occur; e.g., drowsiness in response to medication.

(3) Complications or adverse events. Undesirable outcomes that result from a particular treatment or procedure but were not intended or expected; e.g., infection of a surgical wound.

e. **Signature Consent**. Signature consent is the patient's signature on a VA authorized consent form; e.g., a published numbered VA Form such as OF 522, Request for Administration of Anesthesia and for Performance of Operations and Other Procedures, or comparable form approved by the local VA facility, is required.

f. **Substituted Judgment**. Substituted judgment is a decision made by a surrogate based on knowledge of what the patient would have wanted**.** ***NOTE:*** *If the patient's wishes are unknown, then, and only then, the surrogate's decision must be based on the patient's best interest.*

g. **Surrogate Decision-maker**. A surrogate decision-maker is an individual, organization or other body authorized under VA policy to make health care decisions on behalf of a patient who lacks decision-making capacity (see par. 10).

5. RESPONSIBILITIES

The practitioner is required to obtain the patient's consent for diagnostic and therapeutic procedures. If the patient agrees, family members or others may be included in the informed consent discussion.

a. The practitioner must**:**

(1) Describe the treatment or procedure in language that is understandable to the patient.

(2) Give a clear and concise explanation of the patient's condition or diagnosis. The patient must also be told any reservations the health care team may have about the accuracy of the diagnosis.

(3) Provide information that a patient in similar circumstances would want to know. This includes facts that would be relevant to such a person whether or not disclosure of these facts is standard medical practice.

(4) Describe the name, nature and details of the proposed treatment or procedure and the indications for that course of action. The likelihood of success must also be discussed.

(5) Describe benefits and risks associated with the treatment or procedure including problems that might occur during recuperation. Unless they commonly occur, risks of minor seriousness do not have to be described. The practitioner is not required to explain risks which are extremely remote unless the patient requests that information or unless they may result in disability or death.

(6) Describe clinically indicated and available alternatives. The practitioner must explain why the proposed treatment may be more beneficial to the patient than the alternatives. Benefits and risks associated with the alternative treatment or procedure must also be described. Available alternatives discussed must include the option of no treatment and the anticipated outcome if the patient elects that option.

(7) Identify the practitioner who has primary responsibility for the patient's care. In addition, the names and profession of any other individuals responsible for authorizing or performing the treatment or procedure under consideration must be disclosed.

(8) Advise the patient (beforehand when possible) if another practitioner is substituted for the practitioner named in the initial informed consent.

(9) Advise the patient if the proposed treatment is novel or unorthodox (e.g., off-label use of a drug or medical device) and consent may be refused without jeopardizing the opportunity to receive standard care.

(10) Advise the patient if data obtained from participation in any treatment or procedure will be used for scientific or teaching purposes.

(11) Get specific consent for any aspect of the proposed treatment or procedure that involves research (see M-3, Pt. I, Ch. 9).

b. The informed consent process must include the practitioner's evaluation of the patient's capacity to make health care decisions and must assure the voluntary nature of the patient's participation.

(1) The patient must understand the diagnosis; i.e., the patient must comprehend the nature of the proposed course of treatment or procedure and its associated risks and benefits, alternative options (including no treatment), and the likely outcomes. The patient must understand that a choice is being offered and that the patient may indicate a preference.

(2) The patient must participate in the informed consent process freely without fraud, duress, deceit, or coercion. When medically feasible, the patient must be advised that time may be taken to consult with others or to consider the options further before making a decision.

(3) The patient must be advised that refusal of treatment or revoking of a prior consent may occur without jeopardizing the opportunity for future health care.

(4) Appropriate clinical evaluation must be conducted and documented for any patient whose capacity to make decisions regarding treatment is in question. If it is determined that the patient lacks decision-making capacity and has a surrogate, that surrogate generally assumes the same rights and responsibilities as the patient in the informed consent process.

(5) If the patient lacks decision-making capacity and has no authorized surrogate, specific procedures for obtaining consent will apply (see pars. 10 and 11).

6. DOCUMENTATION OF THE INFORMED CONSENT DISCUSSION

a. **Process.** The informed consent process must be appropriately documented in the medical record.

(1) Signature consent is not required for administration of most drugs or the performance of minor procedures. However, the practitioner must discuss these treatments or procedures with the patient and must document the discussion in a progress note.

(2) For treatments and procedures that require the patient's signature consent, documentation must include a progress note that details the informed consent discussion **and** an OF 522, Request for Administration of Anesthesia and for Performance of Operations and Other Procedures, or other VA authorized consent form signed by the patient and the practitioner who

obtained the consent. In special situations, the consent form may be signed by someone other than the patient (see pars. 9 and 10).

b. **Informed Consent Progress Note.** The progress note documents that the patient had an opportunity for informed participation in decisions concerning the treatment. The progress note must be written by the practitioner who obtains the patient's consent. ***NOTE:*** *To facilitate accurate and complete documentation see Appendix A for a sample overprint progress note.* The progress note must include all of the following specific items:

(1) The date and time the discussion took place and whether consent was or was not given.

(2) The patient's mental status at the time the information was provided and consent given; e.g., alert, sedated, anxious, confused, lethargic, etc.

(3) The practitioner's assessment of whether the patient has decision-making capacity. ***NOTE:*** *If consent is obtained from the patient's surrogate, the practitioner must document that individual's relationship to the patient and the unavailability of any surrogate of higher priority.*

(4) The name(s) of all the practitioner(s) immediately responsible for the performance and, if applicable, the supervision of the treatment or procedure. This means the resident **and** attending, as applicable.

(5) A brief description of the proposed treatment or procedure, if appropriate.

(6) A statement that relevant aspects of the treatment or procedure including indications, risks, benefits, and alternative options have been discussed with the patient in language the patient understood.

(7) A statement that the patient had an opportunity to ask questions and that the patient indicated comprehension of the discussion.

(8) A statement that the patient freely consented to the treatment or procedure without fraud, duress, deceit, or coercion.

(9) If the patient refuses or revokes consent, the progress note must include a statement that the patient's reasons and the expected outcome were discussed (see par 5).

(10) The **legible** signature of the practitioner writing the note.

c. **Signature Consent.** The signature of the patient on the OF 522, or other VA authorized consent form does not eliminate the need for a thorough discussion with the patient to obtain consent before institution of the treatment or procedure. The patient's signature on a VA authorized consent form is required, in addition to documentation of the informed consent discussion in the progress notes.

(1) A properly executed OF 522 or other VA authorized consent form is valid for a period of 30 calendar days. If a significant amount of time has passed before treatment is initiated, the practitioner must re-evaluate the patient and document the patient's current condition in the medical record. The patient or surrogate must be given the opportunity to review the procedure and ask questions. If there is a change in the patient's condition that might alter the diagnostic or therapeutic decision, or the effect on the patient, or constitutes increased risk, the consent is automatically rescinded.

(2) The patient's signature on a VA authorized consent form must be witnessed. The witness's signature only attests to the fact that the witness saw the patient and the practitioner sign the form.

(3) When a patient's or surrogate's signature is indicated on the OF 522, or other VA authorized consent form, by an "X" two adults must witness the act of signing.

(4) The signed OF 522, or other VA authorized consent form, must be filed in the patient's medical record.

7. CONSENT FOR MULTIPLE TREATMENTS OR PROCEDURES

When the patient has consented to a treatment plan that involves multiple treatments or procedures (e.g., chronic hemodialysis, cancer chemotherapy), it will not be necessary to repeat the informed consent discussion and documentation even if treatment extends beyond the 30-day period as long as the course of treatment proceeds essentially as follows:

a. There is no significant deviation from the treatment plan to which the patient consented in the original informed consent discussion.

b. The time required to complete the course of treatment does not become excessive in relation to the treatment involved and normal healing periods.

c. No new or unusual problems or complications have arisen which would require deviation from the original treatment plan, or create increased risk to the patient.

d. The patient does not revoke the initial consent at any time during treatment.

8. REFUSAL OF CONSENT

The patient has the right to refuse any treatment or procedure even if it may increase the risk for serious illness or death. If consent is refused or revoked, the expected clinical outcome must be carefully explained by the practitioner. The patient must be given a reasonable amount of time to consider the consequences of the decision.

a. If the patient's refusal to consent poses a potential hazard to others (e.g., refusal of treatment for tuberculosis), consultation with the Chief of Staff, the Ethics Advisory Committee or Regional Counsel may be appropriate.

b. If known, the practitioner must note the reason(s) for the patient's decision; e.g., religious objections.

9. CONSENT IN MEDICAL EMERGENCIES

a. In medical emergencies, the patient's consent is implied by law. However, if time permits, reasonable attempts to contact the patient's surrogate to obtain consent must be made. If time does not permit, or if the surrogate is not available, such individual(s) must be contacted as promptly as possible after treatment is begun to explain the nature of the treatment or procedure, the indications, and the outcome.

b. The practitioner may provide necessary medical care in emergency situations without the patient's or surrogate's express consent when all of the three following conditions are met:

(1) Immediate medical care is necessary to preserve life or prevent serious impairment of the health of the patient or others; and

(2) The patient is unable to consent to the treatment or procedure; and

(3) The patient has no surrogate or the practitioner determines that waiting to obtain consent from the patient's surrogate would increase the hazard to the life or health of the patient or others.

c. Emergency situations where the consent of the patient is implied must be documented as follows:

(1) The practitioner must write a dated and signed progress note in the medical record documenting:

(a) The patient's inability to provide consent,

(b) The imminent danger to the health of the patient or others,

(c) The decision to proceed with a particular treatment or procedure, and

(d) Whether attempts were made to contact a surrogate.

(2) Whenever treatment is provided in a medical emergency without the patient's or surrogate's express consent, the Chief of Staff must sign the OF 522 or other VA authorized consent form. This signature may be obtained after the clinical intervention when necessary.

10. CONSENT FROM THE PATIENT'S SURROGATE DECISION-MAKER

a. **Substituted Judgment.** In non-emergency situations, consent must be secured from the patient's surrogate when the patient lacks the capacity to make health care decisions.

(1) The practitioner, in consultation with the chief of service, or Chief of Staff, may determine after appropriate medical evaluation that the patient lacks decision-making capacity and is unlikely to regain it within a reasonable period of time. The practitioner must document this determination in the medical record in a signed and dated progress note.

(2) Consultation with a psychiatrist or licensed psychologist must be obtained when the determination that the patient lacks decision-making capacity is based on a diagnosis of mental illness.

(3) Disclosures required by this policy to be made to the patient by the practitioner, must be made to the patient's surrogate to the extent permitted by law (see par. 14).

(4) If feasible, the practitioner must explain the proposed treatment or procedure to the patient even when the surrogate gives consent.

b. **Priority.** Informed consent must be obtained from individuals **in the following priority:**

(1) **Health Care Agent.** The health care agent is the individual named in a Durable Power of Attorney for Health Care (DPAHC) executed by the patient while the patient had decision-making capacity. The health care agent acts on the patient's behalf to make health care decisions, including the use of life-sustaining treatment when the patient is unable to provide consent (see M-2, Pt. I, Ch. 31, and VA Form 10-0137B, VA DPAHC (Durable Power of Attorney for Health Care).

(2) **Legal Guardian or Special Guardian.** A legal guardian or special guardian is a person appointed by a court of appropriate jurisdiction to make decisions for an individual who has been judicially determined to be incompetent. A special guardian is appointed for similar reasons, but makes only decisions concerning the patient's health care.

(3) **Next-of-Kin.** The next-of-kin is a relative (18 years of age or older) who may act as surrogate for the patient in the following priority; it is the spouse, adult child, parent, adult sibling, grandparent, adult grandchild.

(4) **Close Friend.** A close friend is any person 18 years or older (including a relative not listed above) who has shown care and concern for the patient’s welfare and is familiar with the patient's activities, health, religious beliefs and values. The close friend must present a signed written statement (to be filed in the medical record) that describes (with specific examples) that person’s relationship to and familiarity with the patient.

Social Work Service must verify, in a signed and dated progress note, that these requirements have been met.

(5) **No Surrogate Available.** If none of the surrogates listed in preceding subparagraphs (1), (2), (3), and (4) are available, the practitioner may contact Regional Counsel for assistance in obtaining a special guardian for health care or may follow the procedures outlined as follows (see par. 11).

c. **Consent for Minors.** If the patient is considered a minor under state law in the jurisdiction where the VA facility is located, and may not legally consent to medical treatment, consent must be obtained from the patient's parent or legal guardian. ***NOTE:*** *This requirement does not apply to current or former members of the Armed Forces.*

11. CONSENT FOR PATIENTS WITHOUT SURROGATES

This paragraph sets out an alternative process for decision-making on behalf of patients without surrogates. This process takes place primarily within the medical facility.

a. **Treatments and Procedures that Involve Minimal Risk.** Low risk procedures or treatments that are within broadly accepted standards of medical practice do not require the patient's signature consent. As part of good medical practice the practitioner must discuss these measures with the patient. Even if the patient lacks decision-making capacity, the practitioner must attempt to explain the nature and purpose of the proposed treatment. The practitioner must indicate in a signed and dated Progress Note whether it was possible to communicate with the patient and if the patient appeared to understand.

b. **Treatments and Procedures that Require Signature Consent.** This category includes treatments and procedures that require signature consent, but do not involve withholding or withdrawal of life-sustaining treatments. The following information must be documented in the medical record:

(1) Certification by the attending physician, including a statement by Social Work Service, that after reasonable inquiry they have determined that the patient has not designated a health care agent through a DPAHC and has no legally appointed guardian or available and willing next-of-kin or close friend to act as a surrogate who can be located; and

(2) The attending physician indicates participation in and concurrence with the treatment decision in a signed and dated progress note in the medical record; and

(3) The Chief of Service, or designee, provides written concurrence with the treatment decision.

c. **Withholding or Withdrawal of Life-sustaining Treatment.** Implementation of decisions to withhold or withdraw life-sustaining treatments must follow the guidelines set out in M-2,
Part I, Chapter 31, or Chapter 30, whichever is appropriate. The following procedures must be followed and documented in the medical record:

(1) Certification by the attending physician, including a statement by Social Work Service, that after reasonable inquiry they have determined that the patient has not designated a health care agent through a DPAHC and has no legally appointed guardian or available and willing next-of-kin or close friend to act as a surrogate who can be located.

(2) The attending physician indicates participation in and concurrence with the decision in a signed and dated progress note in the medical record.

(3) A multi-disciplinary committee must be convened by the facility Director to consider the validity of the decision to withdraw or withhold life-sustaining treatment(s) and to verify appropriate documentation. An existing ethics advisory committee, a subcommittee of the ethics advisory committee, or an independent group may serve this function. The committee functions as the patient's advocate and may not include members of the treatment team. The committee must be aware of and sensitive to the patient's cultural, ethnic, and religious perspectives. To that end, and to the extent feasible, the committee must include members who are representative of the patient's cultural, ethnic, or religious group. The committee must then submit a written report to the Chief of Staff that describes its findings and recommendations.

(4) The Chief of Staff, or designee, must approve or disapprove the committee's recommendation to withhold or withdraw life-sustaining treatments. The committee's recommendation(s) and the Chief of Staff's decision must be documented in the medical record.

(5) The facility Director must review the decision and may either concur or request review by Regional Counsel. The final decision must be documented in the medical record.

d. **Quality Assessment Review.** Patients who lack decision-making capacity and have no surrogate are an especially vulnerable class of patients. Each VA medical facility must develop a mechanism to review compliance with the preceding decision-making procedures. This may be accomplished by using clinical monitors under a Quality Assessment Program, a review by the ethics advisory committee, or oversight by a separate group constituted specifically for this purpose. The committee or group impaneled to carry out this function may not include persons who participated in the original decision-making process.

12. OBTAINING CONSENT BY MAIL, FAX, TELEPHONE OR TELEGRAM

a. **Consent by Mail or Facsimile (fax).** When informed consent is sought by mail or fax, the practitioner must enclose a typewritten letter addressed to the surrogate with the VA authorized consent form. The letter must provide the same information that would generally be supplied to the surrogate in a face-to-face discussion and must be signed by the practitioner. A copy of the letter must be filed in the patient's medical record. A facsimile copy of a signed consent form is adequate to proceed with treatment. The form that the surrogate actually signed must be returned and filed in the patient's medical record.

b. **Consent by Telephone.** If it is impractical to obtain the surrogate's signature consent, informed consent may be obtained by telephone.

(1) When consent is obtained by phone, the conversation must be audiotaped with the surrogate's permission.

(a) The practitioner must begin the conversation with an introduction, and continue by verifying the identity of the person spoken to; e.g., "This is Dr. Katherine Brown, Chief of Orthopedic Surgery at VA Medical Center (location). Am I speaking to Susan E. Black, the wife of Lee A. Black? Do I have your permission to audiotape this conversation?" Next, the practitioner must establish that individual's authority to act as surrogate, and then proceed with the informed consent discussion.

(b) A typed transcript of the discussion with the date and time of the call must be filed in the patient's medical record. The transcriptionists must sign the document to certify that the transcript is an accurate verbatim account of the audiotaped conversation. The audiotape must be clearly labeled with the:

1. Patient's name,

2. Social Security Number,

3. Date of conversation, and

4. Name of the VA medical facility.

(c) Audiotapes must be kept under lock and key storage by the medical records custodian until replaced by a signed consent form or disposed of in accordance with VHA Records Control Schedule 10-1. ***NOTE:*** *The transcript must remain filed in the patient's medical record.*

(2) If permission to audiotape the discussion is denied, a second VA employee must listen to the conversation. Both the practitioner and the second employee must sign a report of contact that details the conversation. ***NOTE:*** *The report of contact must be filed in the patient's medical record.* The report must include the following information:

(a) The date and time of the call;

(b) The identity of the VA employee(s) who placed the call;

(c) The identity of the person spoken to and that individual's relationship to the patient; and that person's authority to consent on the patient's behalf;

(d) A brief description of the treatment or procedure to be performed and an explanation why treatment is necessary;

(e) A statement that benefits, risks, and alternative treatment options were discussed; and

(f) Whether or not consent was given.

c. **Consent by Telegram.** When necessary, a VA facility may request the surrogate's consent by telegram. The message must identify the facility, the practitioner, the patient and the surrogate, and specifically state the treatment or procedure to be performed. The Chief of Medical Administration Service (MAS), or designee, must verify that the names and other identifying data in the message are accurate. The practitioner must supplement the description contained in the initial request if the surrogate requests more information. ***NOTE:*** *A copy of the original request, any supplemental messages and the surrogate's response must be filed in the patient's medical record.*

13. SPECIAL SITUATIONS WITH SPECIFIC CONSENT REQUIREMENTS

a. **Unusual or Extremely Hazardous Treatments of Procedures.** No patient will undergo any unusual or extremely hazardous treatment or procedure; e.g., that which might result in irreversible brain damage or sterilization, except as provided as follows:

(1) Before treatment is initiated, the patient must be given adequate opportunity to consult with independent specialists, legal counsel or other interested parties of the patient's choosing. The patient's signature on a VA authorized consent form must be witnessed by someone who is not affiliated with the VA health care facility; e.g., spouse, legal guardian , or patient advocate.

(2) If the patient lacks decision-making capacity, consent must be obtained from the patient's surrogate. The surrogate must be permitted to consult with independent specialists, legal counsel, or other interested parties concerning the proposed treatment or procedure. Before treatment is initiated, a multi-disciplinary committee, appointed by the facility Director, must review the surrogate's decision to assure it is consistent with the patient's wishes (or best interest, if the patient's wishes are not known). The committee functions as the patient's advocate and may not include members of the treatment team. The committee must submit its findings and recommendations in a written report to the facility Director. The Director may authorize treatment consistent with the surrogate's decision or request that a special guardian for health care be appointed to make the treatment decision.

(3) If there is no available surrogate, the practitioner may follow the procedures outlined in paragraph 11, or request that a special guardian be appointed to make health care decisions for the patient. ***NOTE:*** *Contact Regional Counsel for assistance.*

NOTE: *The practitioner must document compliance with these procedures in a signed and dated progress note.*

b. **Forced Administration of Psychotropic Drugs.** Administration of psychotropic medication to an involuntarily committed patient against the patient's will must meet Constitutional due process requirements. The practitioner must document compliance with the following procedures in a signed and dated progress note:

(1) The patient or surrogate must be allowed to consult with independent specialists, legal counsel or other interested parties of choice concerning treatment with psychotropic medication.

(2) Any recommendation to administer or continue medication against the patient's will must be reviewed by a multi-disciplinary committee appointed by the facility Director for this purpose. That committee must include a psychiatrist or a physician who has psychopharmacology privileges. The committee functions as the patient's advocate and may not include members of the treatment team. The facility Director must concur with the panel's recommendation to administer psychotropic medications contrary to the patient's wishes.

(3) Continued therapy with psychotropic medication must be reviewed every 30 days.

(4) The patient, or a representative on the patient's behalf, may appeal the treatment decision to a court of appropriate jurisdiction.

c. **Assessment of the Patient for Suspected Abuse or Neglect.** Information and/or other evidentiary material(s) collected during the diagnosis and treatment of a patient who is the suspected victim of abuse or neglect could be used for future prosecutions. The practitioner must assure that the proper consent for diagnosis and treatment is obtained from the patient or surrogate and appropriately documented in the medical record. There are specific conditions that must be met before such information may be disclosed without the patient's consent (see M-1, Pt. I, Ch. 9). Evidentiary material released by the patient will be collected, retained, and safeguarded according to local VA medical facility policy.

d. **Research**. This handbook does not apply to consent for use of investigational drugs and treatments or procedures that involve research (se M-3, Pt. I, Ch. 9).

14. TESTING FOR HUMAN IMMUNODEFICIENCY VIRUS (HIV)

a. **Testing for HIV.** Testing for HIV must be voluntary and must be conducted only with the prior informed and signature (written) consent of the patient or surrogate.

(1) Patients who consent to testing for HIV must sign VA Form 10-1021, Consent for HIV Antibody Testing. This form must be filed in the patient's medical record.

(2) Testing must be conducted for each patient who requests the test, unless medically contraindicated.

(3) Testing must be accompanied by pre-test and post-test counseling.

b. **Pre-test Counseling**. All elements of VA Form 10-1021 must be explained in detail by the practitioner or professional counselor during pre-test counseling. Pre-test counseling must include the:

(1) Policy on non-discrimination in health care services for patients with HIV infection and the health care services available in VA;

(2) Meaning, sensitivity and specificity of the HIV tests;

(3) Potential social ramifications of a positive test result;

(4) Measures to be taken for prevention of HIV transmission;

(5) Limits of the VA policy for maintaining confidentiality of HIV test results;

(6) VA policy on authorized disclosure to a spouse and/or sexual partner; and

(7) VA policy and guidelines on authorized disclosure to public health authorities.

c. **Documentation of Pre-test Counseling.** A signed Progress Note detailing the pre-test counseling must be entered into the medical record. The Progress Note must include:

(1) The date and time that pre-test counseling was conducted and whether signature consent was or was not given;

(2) The patient's mental status and emotional state at the time of counseling;

(3) A brief description of the content covered in counseling;

(4) That the patient had an opportunity to ask questions and to indicate comprehension of the significance and social ramifications of the test; and

(5) The fact that the patient freely consented to testing without duress or coercion.

d. **Post-test Counseling.** Post-test counseling must be adapted to both the test result and the particular needs of the individual patient or subject.

(1) Negative Result. Counseling for a negative result must include, but not be limited to:

(a) The validity of the negative result if the patient is in a group at high risk for HIV infection,

(b) Possible re-testing , and

(c) Reinforcement of risk reduction behaviors.

(2) Positive Result. Counseling for a positive result must include, but not be limited to:

(a) Reinforcement of the availability of VA health care services and community and public health resources;

(b) The advantages of notification of a spouse or other sexual partners of possible exposure to HIV, and

(c) Reinforcement of preventive HIV transmission measures to be taken by the patient.

e. **Documentation of Post-test Counseling**. A signed progress note detailing the post-test counseling encounter must be entered into the medical record. The progress note must include:

(1) The date and time that post-test counseling was conducted and the results of the test;

(2) The patient's mental status and emotional state at the time of counseling;

(3) A brief description of the content covered in counseling;

(4) Documentation that the patient had an opportunity to ask questions and to indicate comprehension of the significance and social ramifications of the test result; and

(5) A list of the referrals made for health care and social services, and plans for future services.

f. **Confidentiality and Disclosure of HIV Status.** VA generated records that reveal the identity, diagnosis, prognosis, or treatment of VA patients related to HIV infection or Acquired Immune Deficiency Syndrome (AIDS) must be kept confidential. This information may not be released without the patient's special written consent unless the disclosure is otherwise authorized by law. Unauthorized release of confidential information, such as HIV test results, may result in criminal penalties and/or substantial fines. ***NOTE:*** *Refer to M-1, Part I, Chapter 9, and consult the local Privacy Act Officer or Regional Counsel when questions arise.*

15. REFERENCES

a. Title 38 United States Code (U.S.C.) § 7331.

b. Title 38 Code of Federal Regulations (CFR) § 17.34.

c. Title 38 CFR § 17.34a.

d. Title 38 U.S.C. § 7332.

e. Title 38 U.S.C. § 7333.

f. Title 38 CFR Part 16.

g. VHA Manual, M-2, Part I, Chapter 30, "Do-Not-Resuscitate (DNR) Protocols."

h. VHA Manual, M-2, Part I, Chapter 31, "Withholding and Withdrawal of Life-Sustaining Treatment."

i. VHA Manual, M-3, Part I, Chapter 9, "Requirement for the Protection of Human Subjects."

j. Accreditation Manual for Hospitals, JCAHO, current edition.

TREATMENTS OR PROCEDURES REQUIRING THE PATIENT'S SIGNATURE CONSENT

NOTE: *The following list is NOT exhaustive. See paragraph 3b of the handbook for a general description of treatments or procedures that require signature consent.*

1. Treatments and Procedures

a. Anesthesia (epidural, spinal, endotracheal);

b. Arthrocentesis;

c. Aversive conditioning (see par. 13 of the handbook);

d. Biopsy, all requiring anesthesia (e.g., breast, liver, muscle, kidney, genito-urinary, prostate, bladder, skin);

e. Blood product transfusion;

f. Bone marrow aspiration or biopsy (sternal, iliac, vertebral puncture);

g. Cardiac catheterization;

h. Cardiac pacemaker electrode insertion (transvenous);

i. Cardioversion (electrical);

j. Central vascular access device insertion (e.g., arterial line, Swan-Ganz catheter, Percutaneous Intravascular Catheter (PIC) line, Hickman catheter);

k. Chemotherapy (for cancer);

l. Cisternograms;

m. Dental extraction;

n. Diagnostic or therapeutic interviews with intravenous (IV) administration of hypnotics;

n. Electrocautery;

o. Electroconvulsive therapy;

p. Endoscopy (e.g., arthroscopy, bronchoscopy, colonoscopy, culdoscopy, cystoscopy, ERCD-endoscopic retrograde cholangioduodenoscopy, esophagoscopy, gastroscopy, laparoscopy, laryngoscopy, sigmoidoscopy, ureteroscopy, urethroscopy);

q. Hemodialysis;

r. Laser therapy;

s. Laser brain tissue ablation;

t. Lumbar puncture;

u. Motor point block;

v. Oral surgical procedures (including gingival biopsy);

w. Paracentesis (abdominal);

x. Peritoneal dialysis

y. Pneumothorax, induced;

z. Psychosurgery;

aa. Photochemotherapy in combination with psoralens or other topical agents;

bb. Radiographic procedures requiring injection of imaging or contrast media (e.g., angiograms, bronchogram, cholangiogram, hysterosalpingogram, myelogram, retrograde pyelogram);

cc. Sterilization of reproductive capacity;

dd. Surgery (of any type, even minor incisions and drainage, excisions of small lesions, needle aspirations, cauterizations, electrocoagulations, fulgurations, suturing, etc.);

ee. Thoracentesis;

ff. Thoracotomy, chest tube, for open drainage;

gg. Tracheostomy;

hh. Transjugular intrahepatic portal stent (TIPS); and

ii. Ultrasound therapy (e.g., lithotripsy).

2. Hazardous Drugs - Antabuse.

3. Investigational Drugs or Procedures. See VHA Manual, M-3, Part I, Chapter 9, "Requirements for the Protection of Human Subjects."

SAMPLE OF AN OVERPRINTED VA FORM 10-0114J, SUPPLEMENT TO PROGRESS NOTE FOR SPECIALIZED DISCIPLINES, SHOWING INFORMED CONSENT DISCUSSION

1. Date of the Discussion:_____ Time of the Discussion:_____

2. Persons present at the discussion:_____

3. Patient's mental status: ___alert ___sedated ___anxious ___confused ___lethargic

4. The patient: ( ) Has decision-making capacity (skip to #6).
   ( ) Does not have decision-making capacity (explain).
   ( ) Unable to formulate/communicate decisions. (Consult Service Chief or Chief of Staff.)
   ( ) Under guardianship.
   ( ) A minor.
   ( ) Secondary to mental illness. (Consultation with psychologist or psychiatrist.)

5. Patient's diagnosis_____

6. Name(s) of the practitioner(s) responsible for performing the treatment or procedure and professional designation:_____

7. Name of Treatment/procedure: _____
   Brief description if appropriate:

8. The following items have been discussed with the patient and/or surrogate (check as appropriate):

   ( ) Treatment and/or procedure has been discussed with the patient and/or surrogate.
   ( ) Indications, risks, benefits, and alternative treatment options have been explained.
   ( ) The patient and/or surrogate was offered an opportunity to ask questions.

9. The patient and/or surrogate (check as appropriate):

   ( ) Consented freely without fraud, duress or coercion
   ( ) The patient and/or surrogate refused consent.
   ( ) Reason(s) known - Explain_____
   ( ) Reason(s) unknown
   ( ) The expected clinical outcome of refusal has been explained to the patient.

10. An OF 522, Request for Anesthesia and for Performance of Operations and Other Procedures, or other VA authorized consent form for this treatment/procedure was signed by the patient/surrogate___yes___no

11. Surrogate decision-maker information:

    Name:_____ Relationship to patient:_____

    Authority:___DPAHC ___Legal and/or Special guardian ___Next-of-kin ___Close Friend

    I certify that no surrogate of higher priority is available.

Signature and Title of Practitioner	Date
Imprint from Patient Data Card	**MEDICAL RECORD** **SUPPLEMENT TO PROGRESS NOTE FOR SPECIALIZED DISCIPLINES-VERTICAL**

VA FORM
SEP 1982(R) **10-0114J**